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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,787	CLAEYS ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 15-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/07/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 7/23/2007. Currently, Claims 1-16 are pending. Claims 8-14 are withdrawn as being drawn to a nonelected invention.

2. The following rejections to Claims 1-7 and 15-16 are applied as necessitated by amendments or are reiterated. Response to arguments follows.

3. This action is FINAL.

Claim Objections

4. Claim 3 is objected to because of the following informalities: In Claim 3 (vii) and (viii) are identical. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-7 and 15-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4, and 16 are indefinite over the phrase "specifically hybridizes" in Claim 3. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids are required to "specifically hybridize" or which hybridization conditions are required to "specifically hybridize".

Claims 3-4, and 16 are indefinite over the phrase "S. aureus specific fragment" in Claim 3. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids specific for S. aureus. It is unclear if the metes and bounds of the phrase are limited to only hybridize to S. aureus and no other species or fragments which bind to S. aureus and to other species.

Claims 3-4, and 16 are indefinite over the phrase "S. aureus specific homologue" in Claim 3. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids specific for S. aureus. The metes and bounds of the phrase are unclear because it is unclear which homologues are specific for S. aureus. It is unclear if the homologues only has nucleic acids which are in S. aureus and no other species or if the homologues have nucleic acids that are present in S. aureus and also other species.

Claims 5-7 and 15 are indefinite over the phrase "hybridizing specifically" and "specifically hybridize" in Claim 5. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids are required to "hybridizing specifically" and "specifically hybridize" or which hybridization conditions are required to "hybridizing specifically" and "specifically hybridize".

Claims 5-7 and 15 are indefinite over the phrase "S. aureus specific homologue" in Claim 5. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids specific for S.

aureus. The metes and bounds of the phrase are unclear because it is unclear which homologues are specific for S. aureus. It is unclear if the homologues only has nucleic acids which are in S. aureus and no other species or if the homologues have nucleic acids that are present in S. aureus and also other species.

Claim 15 is unclear. It is unclear how "components necessary for producing said buffer" limits the claim. It is unclear which components are needed to produce the hybridization buffer.

Claim 16 is indefinite over the phrase "specifically hybridizes". The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear which nucleic acids are required to "specifically hybridize" or which hybridization conditions are required to "specifically hybridize".

Response to Arguments

The reply traverses the rejection. (A) The reply asserts that homologues are defined in the specification (p. 14 2nd paragraph). (B) The reply asserts that it is known in the art that specifically hybridizes refers to hybridization to the recited target as opposed to random or non-specific hybridization (p. 14 3rd paragraph). The reply points to the use of the term "specifically hybridize" in various patents (p. 14-15). The reply asserts that "taxon specific hybridization" or "taxon specific probe" as described in the specification is a probe that only hybridizes to the DNA or RNA from the taxon for which it was designed and not to DNA or RNA from other taxa (p. 15 4th paragraph). (C) The

reply point to various patents which have the phrase "components necessary for producing said buffer" (p. 15 last paragraph and p. 16-p.18).

These arguments have been fully considered but have not been found persuasive.

(A-B) The instant specification discloses "homologues are homologous sequences to SEQ ID No. 1 or 2 or any fragment thereof, localized in the ITS region of any Staphylococcus species". The instant specification does not define "specific homologues". It is still unclear which nucleic acids would be considered specific to S. aureus. It is not clear it these fragments can only detect S. aureus or if the fragments share some sequence identity to other Staphylococcus species.

For example, SEQ ID No. 2 is 97% identical to Staphylococcus xylosus (NCBI GenBank Accession number U90017 December 9, 1997). Therefore any fragment of SEQ ID No. 2 is not going to only hybridize to S. aureus, these fragments share sequence identity to other closely related species.

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Staphylococcus xylosus 16S-23S ribosomal RNA spacer region
Length=283

 Score =  207 bits (112),  Expect = 6e-51
 Identities = 132/142 (92%), Gaps = 5/142 (3%)
 Strand=Plus/Plus

Query  1    TTTGTACATTGAAAACTAGATAAGTAAGT-AAA-ATATAGATTTTACCAAGCAAAACCGA  58
            |||| ||||||||||||||||||||||| ||| ||||||||||||||| ||||||||
Sbjct  100  TTTGNACATTGAAAACTAGATAAGTAAGTAAAATATATAGATTTTACCAAGAAAAACCGA  159

Query  59   GTGAATAAAGAGTTTTAAATAAGCTTGAATTC-ATAAGAAATAATCGCTAGTGTTCGAAA  117
            ||||||  |||||||||||||||||||||||| | || ||||||||||||||||||||||
Sbjct  160  GTGAAT-TAGAGTTTTAAATAAGCTTGAATTCAAAAASAAATAATCGCTAGTGTTCGAAA  218

Query  118  GAACACTCACAAGATTAATAAC  139
            |||||||||| |||||||||
Sbjct  219  GAACACTCACA-GATTAATAAC  239
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Further, the instant specification discloses the detection of Staphylococci in particular S. aureus, S. epidermidis, and S. haemolyticus using SEQ ID No. 17 and 19 (p. 33 lines 4-5). The specification asserts teaches that all S. aureus, S. epidermidis, and S. haemolyticus isolates were detected using SEQ ID No. 17 and 19 (p. 36 lines 10-11). The table on p. 38 indicates which species were detected on a gel, these species include more than just S. aureus.

Therefore, the art shows that SEQ ID No. 1 and 2 share structural identity to more than just S. aureus. Further the specification discloses that probes to these areas detect other species of Staphylococcus. Therefore, it is unclear the metes and bounds of the terms "specifically hybridize", "S. aureus specific fragment", and "S. aureus specific homologue" because it is not clear which nucleotides are required to be specific only to S. aureus.

Although these terms might be found in other patent claims, each application is examined on its own merits. These terms have not been clearly defined in the instant specification and both the art and the instant specification indicate that fragments of these sequences can hybridize to other species of Staphylococcus.

(C). Although these terms might be found in other patent claims, each application is examined on its own merits. It is not clear which components are required in the kit. The instant specification discloses that the LC-FastStart DNA Master Hybridization Probe kit was used (p. 34 lines 18-20). It is not clear it the claim is drawn to all components of the already manufactured kit, the main hybridization buffers, or all

components to make hybridization buffers including salts needed to get the hybridization buffer to the appropriate pH. Therefore, it is not clear which components are required to be included in the kit.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3-7 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is drawn to an isolated nucleic acid that specifically hybridizes to SEQ ID No. 1, or the RNA form of SEQ ID No. 1, or to a fragment of at least 20 nucleotides or any homologue for the detection of staphylococcus. Claim 4 is drawn to an isolated nucleic molecule consisting of SEQ ID No. 17 and 19. Claim 5 is drawn to a set of two probes hybridizing to SEQ ID NO. 1 or 2 or homologues. Claim 6 is drawn to a set of two polynucleotide probes consisting of SEQ ID no. 17 and 19. Claim 7 is drawn to a composition comprising at least one nucleic acid of Claim 1 or a set of two

polynucleotide probes. Claim 15 is drawn to a kit. Claim 16 is drawn to an isolated nucleic acid molecule of at most 100 nucleotides that specifically hybridized to SEQ ID No. 2.

The claims are broadly drawn to any fragment of SEQ ID No. 1 or 2, which can detect staphylococcus.

The claims are further drawn to "at least 20 contiguous nucleotides of SEQ ID No. 1" or any homologue to detect Staphylococcus. Though there is functional language in the claim, the structure is not clearly defined. The claims are drawn to any fragment of 20 mer or greater or any homologue. This broad claim language encompasses a large number of variants and mutations, which are not described in the instant specification. The specification does not define which nucleotides are critical to retain functionality and therefore there is not a clear association between structure and function.

The specification does not prove an adequate written description of the claimed genus of nucleic acids. The claims are broadly drawn to any fragments of at least 20 mer or any homologue; however, the specification only describes SEQ ID No. 1 and 2. The specification does not describe what structure is critical to retain functionality; therefore the specification has not defined the nucleic acids in terms of both structure and function. Therefore, the genus of fragments include any fragment of nucleic acids which share some degree of structural identity to S. aureus in which hybridization occurs.

The phrase "specifically" does not limit the genus of potential fragments. The specification has not provided guidance as to how much sequence identity a fragment needs to maintain to be specific for S. aureus. It is not clear if the sequence can hybridize to other staphylococcus or if the fragments need to only hybridize to S. aureus. The specification has not identified which sequences would be used in an oligonucleotide such that the oligonucleotide would hybridize only to S. aureus, but to no other sequence.

Therefore the claims are drawn to any fragment that specifically hybridizes, however, the specification has not provided any guidance as to which fragments would hybridize only to S. aureus. The specification describes only a few probes derived from SEQ ID No. 1 and 2 such as SEQ ID No. 17 and 19. However, the specification has not provided which structures are functionally correlative to "specifically hybridizes". Because the phrase is not defined in the specification, the genus of nucleic acids include any nucleic acid fragment which hybridizes to S. aureus including any fragments which hybridize to other staphylococcus. Therefore since the function has not been adequately defined the genus encompasses any fragment, which has some degree of hybridization to S. aureus.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The sequences encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly diverse. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

The reply traverses the rejection. The reply asserts that the claims relate to S. aureus and S. aureus specific fragments (p. 20 last paragraph).

This has been thoroughly reviewed but has not been found persuasive.

As discussed above, the claimed sequences are not limited to only fragments, which hybridize to S. aureus, but to any fragment that detects S. aureus even if the fragment hybridizes to other Staphylococcus species. As discussed in the response to arguments in the 35 USC 112/ 2nd paragraph section, the art teaches structures which are 97% identical to SEQ ID No. 2 (e.g. fragments of at least 20 base pairs) which would hybridize to both S. aureus and other staphylococcus species. Further the instant specification teaches that the probes used in the instant specification detect many staphylococcus species and therefore are not functionally limited to only hybridization to S. aureus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes et al. (US Patent 6312903 November 6, 2001).

With regard to Claim 1 and 2, Jannes et al. teaches sequences for the detection of eubacterial taxa (abstract). Jannes et al. teaches a sequence (SEQ ID No. 142) which is 383 nucleotides in length. Nucleotides 174-316 of SEQ ID No. 142 are identical to SEQ ID Nos. 1 and 2 of the instant application. It is noted that SEQ ID No. 1 of the instant claims comprise symbols, which give variability to particular nucleotides at a particular position. For example nucleotide 141 is an "N" which would match at that position any sequence which has "A", "G", "C", or "T".

Though Jannes et al. does not teach a nucleic acid molecule consisting of SEQ ID No. 1 or 2, only a 383 bp fragment which comprises SEQ ID No. 1 and 2, Jannes et al. does suggest a method in which various fragments of the target gene are detected using probes. Jannes et al. teaches the length of the target nucleic acid sequence and,

accordingly, the length of the probe sequence can also be important. In some cases, there may be several sequences from a particular region, varying in location and length, which will yield probes with the desired hybridization characteristics. In other cases, one sequence may be significantly better than another which differs merely by a single base. While it is possible for nucleic acids that are not perfectly complementary to hybridize, the longest stretch of perfectly complementary base sequence will normally primarily determine hybrid stability (Column 5 lines 15-67 and Column 6 lines 1-21).

With regard to Claim 3, Jannes et al. teaches that SEQ ID NO. 142 detects S. aureus (Column 3 lines 40-43 and figure 67). Jannes et al. teaches probes that specifically hybridize to SEQ ID NO. 142 (at least 20 contiguous nucleotides of SEQ ID No. 1) such as STAU-ICG1 (Seq ID NO. 53 of Jannes et al.) (Table 1a Column 55).

With regard to Claims 4 and 6, though Jannes et al. does not specifically teach probe of SEQ ID No. 17 and 19, Jannes et al. teaches a method which to make equivalents of SEQ ID No. 17 and 19. Jannes et al. does not specifically teach the probe set of SEQ ID No. 17 and 19, he does suggest the fragmentation of a larger fragment into smaller oligonucleotide probes for the detection of staphylococcus species.

Jannes et al. provides guidance to determining wherein the spacer region probes should be designed. Jannes et al. teaches from the alignment of the spacer region, regions of divergence can be defined, from which probes with desired hybridization characteristics are designed, according to guidelines known the skilled artisan (Column 4 lines 29-32).

"First, the stability of the [probe:target] nucleic acid hybrid should be chosen to be compatible with the assay conditions. This may be accomplished by avoiding long A and T rich sequences, by terminating the hybrids with G:C base pairs, and by designing the probe with an appropriate Tm.

Conditions such as ionic strength and incubation temperature under which a probe will be used should also be taken into account in constructing a probe.

It is desirable to have probes which hybridize only under conditions of high stringency. Under high stringency conditions only highly complementary nucleic acid hybrids will form; hybrids without a sufficient degree of complementarity will not form.

Second, probes should be positioned so as to minimize the stability of the [probe nontarget] nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complemenarity to non-target organisms, avoiding GC rich regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible.

The length of the target nucleic acid sequence and, accordingly, the length of the probe sequence can also be important. In some cases, there may be several sequences from a particular region, varying in location and length, which will yield probes with the desired hybridization characteristics. In other cases, one sequence may be significantly better than another which differs merely by a single base. While it is possible for nucleic acids that are not perfectly complementary to hybridize, the longest stretch of perfectly complementary base sequence will normally primarily determine hybrid stability. While oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 10 to 50 bases in length and are sufficiently homologous to the target nucleic acid.

Third, regions in the target DNA or RNA which are known to form strong internal structures inhibitory to hybridization are less preferred. Likewise, probes with extensive self-complementarity should be avoided. (Column 5 lines 15-67 and Column 6 lines 1-21)."

With regard to Claim 5 and 7, Jannes et al. teaches that probes for detection should be used in sets comprising at least 2 probes (Column 11 lines 66-67). Jannes et al. teaches probe sets which hybridize to SEQ ID No. 142 (which comprises SEQ ID No. 1 and 2 of the instant application). Jannes et al. teaches a probe SEQ ID No. 53 that hybridizes to a region of SEQ ID No. 1 and 2 (Column 41 lines 20-50). Jannes et al.

teaches other probes which hybridize to SEQ ID No. 142 (Column 41 lines 20-50). Particularly, SEQ ID no. 56 hybridizes less than 25 mer away from SEQ ID No. 53 on the target of SEQ ID No. 142. These probes can be used in conjugation with probe of SEQ ID NO. 53, therefore, Jannes et al. teaches that probes can be used in a set in which the probes are 25 mer or less.

With regard to Claim 15, Jannes et al. teaches a kit for the detection of at least one microorganism (staphylococcus) comprising probes and hybridization buffer (Column 47 lines 50-65, SEQ ID No. 142, and Column 55-56).

With regard to Claim 16, Jannes et al. teaches a probe (SEQ ID No. 53). Jannes et al. teaches the probe is 30 mer in length. SEQ ID No. 53 is 100% identical to the instant SEQ ID No. 2; therefore it would hybridize to SEQ ID No. 2.

Therefore, the ordinary artisan would have been motivated to amplify any portion of SEQ ID No. 1452 (including fragments consisting of SEQ ID No. 1 and 2 of the instant application) and to select any number of oligonucleotide fragments from the 16S-23S spacer region including SEQ ID Nos 17 and 19, which are fragments of SEQ ID No. 142. The art of designing probes (oligonucleotides) at the time the invention was made was very well described in the art. Designing probes that are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes, see Jannes et al. Moreover there are many Internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information

necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. The claimed probes are prima facie obvious over the cited references in the absence of secondary considerations, given the extensive teachings in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the amplified sequence of Jannes et al. and design constraints of probes taught by Jannes et al. to obtain equivalent alternative probes of the claimed invention. The ordinary artisan would be motivated to have designed and test new probes to obtain additional oligonucleotides that function to detect Staphylococcus and identify oligonucleotides with improved properties.

Response to Arguments

The reply traverses the rejection. The reply asserts that having a 35 USC 112, first paragraph Written Description rejection and an art rejection is contratory (p. 20 3rd paragraph). The reply asserts that the cited patent fails to teach an isolated nucleic acid molecule consisting of SEQ ID No. 1 or 2 (p. 20 last paragraph). The reply asserts that the SEQ ID NO. 142 of the cited patent will not specifically hybridize to SEQ ID No. 1 or 2 because the sequence contains additional 240 bases, which would be non-specific (p. 21 1st full paragraph). The reply asserts that SEQ ID NO. 53 from the cited patent reacts with all Staphylococcus species tested and therefore is not a S. aureus specific sequence (p. 21 2nd full paragraph). The reply asserts that in the instant application SEQ ID No. 1 and 2 were designed so that they did not detect other Staphylococcus species and that they were highly sensitive (p. 22 last two paragraphs). The reply

asserts that the sequences in the instant application are S. aureus specific (p. 23 1st two paragraphs).

These arguments have been fully considered but have not been found persuasive.

The rejection of the claims under both 35 USC 112/Written Description and 35 USC 103(a) is not contradictory. The rejection of the claims under 35 USC 112/ Written Description states that the claims encompass a large number of possible species, however, the specification has not described the structure/function correlation in such a way that the skilled artisan would be able to determine which nucleic acid fragments would be encompassed by the claims. Whereas, the 35 USC 103(a) states that Jannes et al. provides teachings and motivation to make probes to the 16S region of S. aureus to detect S. aureus in a sample.

Though Jannes et al. does not teach an isolated nucleic acid molecule consisting of SEQ ID no. 1 or 2, Jannes et al. does teaches SEQ ID No. 142 which comprises SEQ ID NO. 1 and 2. Jannes et al. further provides guidance to amplify any size targets in order to use probes to detect staphylococcus species. Therefore it would be obvious to modify the teaching of Jannes et al. to amplify any fragment of SEQ ID NO. 142 including the fragments of the instant specification SEQ ID No. 1 and 2 in order to detect staphylococcus in a sample.

SEQ ID no. 142 comprises SEQ ID No. 1 and 2, and therefore would specifically hybridize to SEQ ID No. 1 and 2. It is not clear the definition of "specifically hybridizes"

the reply is using to assert that because there are more bases that SEQ ID No. 1 and 2 that it would not specifically hybridize. Further it is noted that SEQ ID No. 142 is derived from an S. aureus isolate so it would detect S. aureus.

The reply seems to be asserting that the claims are limited to fragments, which only hybridize to S. aureus, however, the claims more broadly encompass any fragments, which hybridize to S. aureus but also to other Staphylococcus species. As discussed in the response to arguments in the 35 USC 112/ 2nd paragraph section, the art teaches structures which are 97% identical to SEQ ID No. 2 (e.g. fragments of at least 20 base pairs) which would hybridize to both S. aureus and other staphylococcus species. Further the instant specification teaches that the probes used in the instant specification detect many staphylococcus species and therefore are not functionally limited to only hybridization to S. aureus.

The reply asserts that SEQ ID NO. 1 and 2 were designed to detect only S. aureus and not any other Staphylococcus species. However, as shown in the specification the detection was to more than S. aureus. The instant specification discloses the detection of Staphylococci in particular S. aureus, S. epidermidis, and S. haemolyticus using SEQ ID No. 17 and 19 (the probes which detect SEQ ID NO. 1 and 2) (p. 33 lines 4-5). The specification asserts teaches that all S. aureus, S. epidermidis, and S. haemolyticus isolates were detected using SEQ ID No. 17 and 19 (p. 36 lines 10-11). The table on p. 38 indicates which species were detected on a gel, these species include more than just S. aureus. Therefore the instant specification clearly shows that many species of Staphylococcus were detected.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

/Jehanne Sitton/

Primary Examiner

10/12/2007